K 123470

APR 29 2013

Section 5: 510 (k) Summary

510 (k) Owner:

PAS Systems International, Inc
1616 Princess Anne St
Fredericksburg, VA 22401
Phone: (540) 372-3431
Fax: (540) 372-7647

Contact Person: Jarel R. Kelsey, President

Date Prepared: 02-06-2013

Device Name:

Trade Name: PAS Alcovisor® Satellite™ Breath Alcohol Analyzer *and* PAS Alcovisor® Mars™ Breath Alcohol Analyzer
Common Name: Breath Alcohol Test System
Classification Name: Devices, Breath Trapping, Alcohol
Regulation Number: 21 CFR 862.3050
Classification Product Code: DJZ

Indications for Use:

The PAS Alcovisor® Satellite™ Breath Alcohol Analyzer is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

The PAS Alcovisor® Mars™ Breath Alcohol Analyzer is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

Predicate Device Summary:

The PAS Alcovisor® Satellite™ Breath Alcohol Analyzer and the PAS Alcovisor® Mars™ Breath Alcohol Analyzer devices are claimed to be substantially equivalent to the AlcoHawk PT500 (510 (k) Number K080848).

Device Description:

The PAS Alcovisor® Satellite™ Breath Alcohol Analyzer and the PAS Alcovisor® Mars™ Breath Alcohol Analyzer are breath alcohol test systems designed to sample a user's deep lung breath in order to test for the presence of alcohol. The sensor is an electrochemical fuel cell which will only respond to alcohol. After the user blows into the device using a disposable mouthpiece, for 3-4 seconds, a small sample of breath is drawn into the fuel cell by an automatic pump and a chemical reaction between the alcohol and fuel cell occurs. This reaction generates an electrical current which is directly related to the amount of alcohol in the sample. The current is then converted to a Blood Alcohol Concentration (BAC) level and displayed for the user. The relationship between alcohol in a person's deep lung breath and in their blood is well established using Henry's law, which gives a ratio of 2100:1.

The Satellite™ and Mars™ are handheld devices made from durable plastic with an internal circuit board. The Satellite™ uses an internal rechargeable battery and the Mars™ uses three AAA batteries.

Table 1: Summary of Substantial Equivalence to Predicate Device:

Feature	Predicate : AlcoHawk PT500	PAS Alcovisor Satellite	PAS Alcovisor Mars
Indication for Use	Intended to measure alcohol in human breath. Measurements obtained in this device are used in the diagnosis of alcohol intoxication.	This device is intended to measure alcohol on human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.	This device is intended to measure alcohol on human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.
Sensor	Electrochemical Fuel Cell	Electrochemical Fuel Cell	Electrochemical Fuel Cell
Mouthpiece	Single Use Disposable	Single Use Disposable	Single Use Disposable

Power Source	2 – AA Batteries	An Internal Rechargeable Battery	3 – AAA Batteries
Dimensions	5 in x 2.63 in x 1.25 in	4.75 in x 1.5 in x 1.46 in	4.2 in x 2.0 in x 0.70 in
Construction	Plastic Case with internal circuit board.	Plastic Case with internal circuit board and battery	Plastic Case with internal circuit board
Weight	5.2 oz (with batteries)	4.2 oz	4.0 oz (with batteries)
Warm-up Time	10 seconds	5 seconds	5 seconds
Measurement Site	Mouth	Mouth	Mouth
Accuracy	0.01%	0.01% up to 0.100 and +/- 10% above 0.100%	0.01% up to 0.100 and +/- 10% above 0.100%
Battery Life	200 Tests	500 tests (on full charge)	500 tests
NHTSA (DOT)-Approval	Yes	Yes	Yes
Intended User	General Public	General Public	General Public

Conclusion:

The safety and effectiveness of the PAS Alcovisor® Satellite™ and the PAS Alcovisor® Mars™ devices are inherent in the device designs and have been verified through consumer field evaluations and EMC testing. The ability of both the PAS Alcovisor® Mars™ and the PAS Alcovisor® Satellite™ to measure alcohol content accurately was demonstrated by the tests conducted by the US Department of Transportation (National Highway Traffic Safety Administration (NHTSA)) for approval as an Alcohol Screening Device. Both devices also have the same intended use, with few technological differences, as the predicate device. To ensure safe use of these devices, comprehensive operating instructions are provided as well as an 800 number with qualified customer service staff on hand to guide and answer questions. In conclusion, both the Satellite™ and Mars™ are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2013

PAS Systems International, Inc.
C/O Jarel R. Kelsey
1616 Princess Anne Street
FREDERICKSBURG VA 22401

Re: K123470
Trade/Device Name: PAS Alcovisor Satellite Breath Alcohol Analyzer
PAS Alcovisor Mar Breath Alcohol Analyzer
Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: I
Product Code: DJZ
Dated: February 06, 2013
Received: February 19, 2013

Dear Mr. Kelsey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123470

Device Name: PAS Alcovisor Mars Breath Alcohol Analyzer
PAS Alcovisor Satellite Breath Alcohol Analyzer

Indications for Use:

PAS Alcovisor Mars Breath Alcohol Analyzer
The PAS Alcovisor Mars Breath Alcohol Analyzer is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

PAS Alcovisor Satellite Breath Alcohol Analyzer
The PAS Alcovisor Satellite Breath Alcohol Analyzer is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

Prescription Use _____ And/Or Over the Counter Use __X__.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.04.29 12:51:42 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123470